DETAILED ACTION

Applicant's amendments filed 6/21/2010 are acknowledged and entered.

Status of Claims

Claims 6-9, 14-16, 21, 23, 24 and 26 are cancelled. Claims 1-5, 10-13, 17-20, 22

and 25 are currently pending. Claims 17-20, 22 and 25 are withdrawn. Claims 1-5 and

10-13 are examined on the merits.

Withdrawn Rejections/Objections

Rejections and/or objections not reiterated from previous office actions are

hereby withdrawn in view of the amendments filed 6/21/2010. The following rejections

and/or objections are either reiterated or newly applied. They constitute the complete

set presently being applied to the instant application.

Information Disclosure Statement

The information disclosure statement filed 6/21/2010 is acknowledged. A signed

copy of the corresponding 1449 form has been included with this Office action.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of
matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the
conditions and requirements of this title.

Claims 1-5 and 10-13 are rejected under 35 U.S.C. 101 because the claimed

invention is lacks patentable utility.

The instant claims 1-5 are drawn to a method for searching for a base sequence in genes, using an apparatus, comprising allowing the apparatus to search for the base sequence in base sequences consisting of: base sequences in each of exons of the genes, and base sequences straddling exon borders in each of the genes having a plurality of exons. Further embodiments, claims 10-13, include an apparatus for searching for a specific base sequence comprising a storage for storing base sequences and a searcher for searching for a base sequence.

The claims are directed to a method of searching for a base sequence wherein the sequence appears to be random. While there is a well established utility for methods of searching for consensus sequences, or for sequences which have similarity to sequences with established utility, such as active sites of enzymes or binding sites of receptors, there is no well established utility in the prior art for searching for random "base sequences." The instant specification discloses a search using a union of sets of exon base sequences and a set of border base sequences that straddle exon borders in the expressed gene formed by a plurality of exons. If the base sequence appearing in an expressed gene sequence is specific, i.e. appears only in the targeted gene and does not appear in another gene, the number of search results is one and if not, the number of search results is multiple. By examining the search result, determination of whether the base sequence is the specific base sequence is possible (page 4, last paragraph; page 7, first paragraph). However, the instant claim 1, only provides "allowing the apparatus to search for the base sequence in base sequences" in line 15; and the instant claim 10 only provides "a searcher for searching for a base sequence" in

line 10. Providing a method or apparatus that only searches for a base sequence

without producing a result, or indication of particular information (e.g. base sequences

comprising exons found within an **expressed** gene sequence), is not a specific utility

because there is no specific utility for searching for a (random) base sequence.

Searching for a sequence does not provides a substantial utility because once a base

sequence is found, further research would be required to find a use for it. Therefore

there is no immediate benefit to the public and thus no substantial utility.

Claims 1-5 and 10-13 are also rejected under 35 U.S.C. 112, first paragraph.

Specifically, since the claimed invention is not supported by either a specific and

substantial asserted utility or a well established utility for the reasons set forth above,

one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed
> or described as set forth in section 102 of this title, if the differences between the
> subject matter sought to be patented and the prior art are such that the subject
> matter as a whole would have been obvious at the time the invention was made
> to a person having ordinary skill in the art to which said subject matter pertains.
> Patentability shall not be negatived by the manner in which the invention was
> made.

The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1.   Determining the scope and contents of the prior art.
2.   Ascertaining the differences between the prior art and the claims at issue.
3.   Resolving the level of ordinary skill in the pertinent art.
4.   Considering objective evidence present in the application indicating
      obviousness or nonobviousness.

Claims 1-5 and 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable

over Levenkova et al. (Bioinformatics, 2004, 20(3), 430-432) (IDS filed 10 August 2009)

in view of Sakharkar et al. (Nucleic Acids Research, 2000, 28(1), 191-192).

The instant claims 1 and 10 are drawn to a method and apparatus for searching

for a base sequence in base sequences consisting of: base sequences in each of exons

of the genes, and base sequences straddling exon borders in each of the genes having

a plurality of exons. Claim 10 further provides an apparatus which includes a storage

and searcher.

Regarding claims 1 and 10, Levenkova et al. teaches a target gene sequence is

scanned for candidate siRNA sequences, then BLAST searches of candidate siRNA are

performed against databases, wherein a candidate siRNA sequence is considered

gene-specific if it matches a Unigene cluster of sequences, (abstract; page 430, right

column - page 432, left column, first paragraph; Figure 1), which meets the instant claim

limitation of searching for a base sequence. Levenkova et al. selects targeted regions

that border an expressed gene, e.g. nucleotides around an AUG start site, (page 430,

right column; Figure 1), which meets the instant claim limitation searching for border

base sequences, i.e. base sequences straddling exon borders. Levenkova provides

programs such as BLAST and TOOL, (pages 430 and 432; Figure 1), which are

computerized programs/methods, and thus suggest a computerized apparatus and

program for performing the method of Levenkova et al.

Levenkova et al. does not teach base sequences in each of exons of the genes

or base sequences straddling exon borders.

Sakharkar et al. provides an exon/intron (ExInt) database that incorporates

information on the exon/intron structure of eukaryotic genes, (abstract; page 191, right

column, last paragraph). Sakharkar et al. teaches phase and position for introns

interrupting the coding sequence, and the numbers, size and length of protein encoding

exons, (page 191, right column), which meets the instant claim limitation of base

sequences in each of exons of the genes or base sequences straddling exon borders.

Regarding claims 2 and 11, Levenkova et al. shows the position of the AUG start

codon and start and end positions, used in the identification of sequences within the

databases, (page 430, right column; Figure 1). Sakharkar et al. shows attribute

information including position of introns within the coding sequence, (page 191, right

column, last paragraph).

Regarding claims 3 and 12, Levenkova et al. provides BLAST searches that

utilize user-specified parameters, e.g. number of mismatches in alignment, length of the

match between the SiRNA and search hits, then clusters the "hits" from the BLAST

query to remove redundancy, (page 430, right column, last paragraph – page 432, left

column, first paragraph; Figure 1), which suggests the integration of overlapped

sequences.

Regarding claims 4, 5 and 13, Levenkova et al. uses BLAST searches using

parameters for short nearly identical sequences, user-specified number of mismatches

in alignment and length of the match between siRNA and hits, and filters the results of

the search for matching sequences with % similarity, (page 430, right column, last

paragraph – page 432, left column, first paragraph; Figure 1).

It would have been obvious to one of ordinary skill in the art at the time of the

instant invention to modify the gene specific siRNA selector of Levenkova et al. with the

Exon/Intron database by Sakharkar et al. because while Levenkova et al. provides

expressed sequence tag (EST) database (Figure 1), Sakharkar et al. shows that the

ExInt database provides intron/intron organization of eukaryotic genes present in

GeneBank and organizes data for easy access and retrieval on a larger scale, (page

191, left column, first paragraph).

Response to Arguments

Applicant's arguments filed 7/23/2010 have been fully considered but they are

not persuasive.

Applicants argue that Levenkova fails to disclose [a] set of base sequences that

include sets of exon and border sequences. Applicants argue Sakharkar also fails to

disclose the base sequences straddling exon borders. Applicant argues that the

information provided in Sakharkar for exon/intron structure does not make the base

sequences straddling exon borders obvious. Applicant argues that Rouillard also fails

to disclose the missing elements, therefore each reference alone or in combination fails to make the claims obvious.

In response to applicant's argument that Levenkova fails to disclose [a] set of base sequences that include sets of exon and border sequences, Levenkova et al. selects targeted regions that border an expressed gene, e.g. nucleotides around an AUG start site, (page 430, right column; Figure 1), which at least suggests the instant claim limitation searching for border base sequences, i.e. base sequences straddling exon borders. In response to applicant's arguments that Sakharkar fails to disclose the base sequences straddling exon borders, and that the information provided in Sakharkar for exon/intron structure does not make the base sequences straddling exon borders obvious, Sakharkar is relied upon for teaching the positions and sequences of introns and exons of a coding sequence, (page 191, right column), which suggests that base sequences in exons and border base sequences would be encompassed in the exon/intron database. The argument that Rouillard also fails to disclose the missing elements is moot because Rouillard was relied upon for limitations of now cancelled claim 8. All limitations of the instant claims are made obvious by the cited art.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LARRY D. RIGGS II whose telephone number is

(571)270-3062. The examiner can normally be reached on Monday-Thursday, 7:30AM-5:00PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/LDR/
Larry Riggs
Examiner, Art Unit 1631

/Marjorie Moran/
Supervisory Patent Examiner, Art Unit 1631